Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effects of intravenous Dexamethasone with intravenous Acetaminophen in ovarian cyst surgery on pain, nausea and vomiting

Protocol summary

Study aim
Comparison of the effects of intravenous Dexamethasone with Acetaminophen in ovarian cyst surgery on pain, nausea and vomiting

Design
Clinical trial, with parallel groups, double-blind, randomized, phase 3 on 42 patients.

Settings and conduct
In this randomized double-blind clinical trial performed on 42 women undergoing Ovarian cysts surgery in Mahzad hospital in Urmia, patients in two groups of 21 will randomly receive intravenous Dexamethasone 0.1 mg/kg or intravenous Acetaminophen 15 mg/kg. Patients and statistical analyzers will be unaware of group assignments.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Satisfaction to participate in the study, age between 18 to 65 years.Lack of sensitivity to Dexamethasone and Acetaminophen-Exclusion criteria:Having liver, kidney and heart disease

Intervention groups
Intervention 1: Intravenous Dexamethasone 0.1 mg/kg (Iran Rasht pharmaceutical company) Intervention 2: Intravenous Acetaminophen 15 mg/kg (Osveh company)

Main outcome variables
Pain, nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201207049639N7**
Registration date: **2022-03-26, 1401/01/06**
Registration timing: **prospective**

Last update: **2022-03-26, 1401/01/06**
Update count: **0**

Registration date
2022-03-26, 1401/01/06

Registrant information

Name
Hadi Houshyar

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-22, 1401/02/02

Expected recruitment end date
2022-07-25, 1401/05/03

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of intravenous Dexamethasone with intravenous Acetaminophen in ovarian cyst surgery on pain, nausea and vomiting

Public title
Effect of intravenous Dexamethasone with intravenous Acetaminophen on pain, nausea and vomiting

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Satisfaction to participate in the study Age between 18 to 65 years Lack of sensitivity to Dexamethasone and Acetaminophen

Exclusion criteria:

Having liver, kidney and heart disease

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will conduct based on permuted block randomization method. Each block will have capacity for 4 subjects; it means we will have 10 blocks and one block of 2 subjects (Totally 42 patients). Then, within each block, subjects will be randomly assigned to Dexamethasone and Acetaminophen group . Random assignment will be done using a random number table

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were unaware of their allocation into the intervention groups and the statistical analyzer received the data as codes, not the actual grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Urmia University of Medical Sciences

Street address

Urmia University of Medical Sciences, Resalat Street, Jahad Ave., Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2023-03-02, 1401/12/11

Ethics committee reference number

IR.UMSU.REC.1400.467

Health conditions studied

1

Description of health condition studied

Ovarian cysts

ICD-10 code

N83.20

ICD-10 code description

Unspecified ovarian cysts

Primary outcomes

1

Description

Pain

Timepoint

15 minutes, 0.5, 1, 2, 3, 4, 5 and 6 hours after entering recovery

Method of measurement

Visual Analogue scale

Secondary outcomes

1

Description

Nausea and vomiting

Timepoint

It is recorded up to 6 hours after the surgery if observed

Method of measurement

Observation

Intervention groups

1

Description

Intervention group 1: Intravenous Dexamethasone 0.1 mg/kg (Iran Rasht pharmaceutical company) 15 minutes before finishing the surgery

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous Acetaminophen 15 mg/kg (Osveh Company) 15 minutes before finishing the surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Mahzad Women's Medical Center

Full name of responsible person
Dr. Hadi Hooshyar

Street address
Mahzad Women's Medical Center; Hasani street, Urmia, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Iraj Mohebbi

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Urmia University of Medical Sciences; Resalat street; Jahad Blvd; Urmia; Iran.

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
Dr. Hadi Hooshyar

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Shahid Motahhari Hospital; Kashani street; Urmia; Iran.

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available